Federalism and Patient Protection: Changing Roles for State and Federal Government

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Occasional Paper Number 28

Assessing the New Federalism
An Urban Institute Program to Assess Changing Social Policies

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This report is part of the Urban Institute's *Assessing the New Federalism* project, a multiyear effort to monitor and assess the devolution of social programs from the federal to the state and local levels. Alan Weil is the project director. The project analyzes changes in income support, social services, and health programs. In collaboration with Child Trends, the project studies child and family well-being.

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Assessing the New Federalism

Assessing the New Federalism is a multiyear Urban Institute project designed to analyze the devolution of responsibility for social programs from the federal government to the states, focusing primarily on health care, income security, employment and training programs, and social services. Researchers monitor program changes and fiscal developments. In collaboration with Child Trends, the project studies changes in family well-being. The project aims to provide timely, nonpartisan information to inform public debate and to help state and local decisionmakers carry out their new responsibilities more effectively.

Key components of the project include a household survey, studies of policies in 13 states, and a database with information on all states and the District of Columbia, available at the Urban Institute's Web site. This paper is one in a series of occasional papers analyzing information from these and other sources.

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Introduction

As indemnity health insurance has given way to managed care in the 1990s, state legislatures and Congress have considered an array of patient protection measures. Also called "consumer protection" acts or "Patients' Bills of Rights," such enactments respond to fears that some managed care practices too often mistreat enrollees (Blendon et al. 1998, Enthoven and Singer 1998). State legislators have imposed standards or processes on insurers and managed care organizations (MCOs), such as a minimum 48-hour hospital stay for childbirth, access to the emergency room or to specialists, and appeals processes for patients denied payment for care. Between 1996 and 1998, nearly 600 bills regulating MCOs were introduced in state houses across the country, and at least some provisions were enacted in every state (Stauffer 1998d).

Patient protection is a federal issue as well as a state one. At the federal level, many patient protections have already been imposed by legislation or Executive Order (White House 1998). The 105th Congress introduced some 50 bills focused on patient protection—many addressing only one issue, but others seeking comprehensive change. By mid-February 1999, the 106th Congress had introduced more than 10 comprehensive managed care reform bills.

How much practical difference additional federal legislation would make depends on both federal action and state conditions. Federal proposals vary in the portion of the population targeted for reform, the specific protections advanced, and the provisions for enforcement. State conditions vary in the amount and types of existing regulation and the types of coverage now in effect. For example, where there is little managed care penetration, managed care regulation will make little immediate difference. Where there is high self-insurance, new federal rules will matter greatly. Further, some enforcement responsibility might shift from states to federal

agencies for insured managed care, and new federal enforcement would apply to self-insured managed care.

This paper begins by describing patient protection provisions already enacted by states and proposed in the three prominent federal approaches—Republican, Democratic, and bipartisan. It then assesses the impact federal legislation might have in 13 representative states, based on the relative importance of managed care in each state and existing state regulation. The paper also discusses enforcement and liability issues. The conclusion highlights important differences among the competing federal proposals and the most notable changes each would make for states.

Background: Managed Care Backlash, State Regulation, and ERISA Limits on States

The political push for patient protection legislation has followed a rapid shift from relatively unrestrained indemnity coverage to managed care, which now enrolls more than 75 percent of the privately insured (Ginsburg and Gabel 1998). A consumer backlash has arisen in response to the restrictions imposed by managed care, a relatively unfamiliar form of coverage. Often, enrollees did not choose these restraints, as many employers offer only one option for health coverage (Blendon et al. 1998, Gawande et al. 1998).

Many health care providers have also supported regulation of managed care because of its impact on clinical autonomy (and on provider fees). In fact, an early entry in the current round of legislation was the American Medical Association's (AMA's) model Patient Protection Act advanced in the early and mid-1990s. Originally, the AMA endorsed requirements that managed care networks be open to all physicians willing to participate, which would greatly inhibit plans' ability to contract selectively with providers, a key tool in cost and quality control (Marsteller et al. 1997).

There is a tension between the views that these laws "protect patients" versus "restrict managed care." Protecting patients seems like an unequivocally good notion (even though these laws apply only to insured patients). But regulating MCOs may also risk undermining their ability to control health spending or impede MCO growth. On the one hand, increased regulation has been supported by media attention to some bad outcomes (Brodie et al. 1998, HARP 1999b) and a widely expressed desire among patients for more power vis à vis their managed care plans. On the other hand, there is considerable market demand for managed care, which is often credited with having slowed health care inflation (Ginsberg and Gabel 1998), with little or no effect on quality (Miller and Luft 1994, 1997).

States are traditionally responsible for regulation of insurance and of medical quality, but state authority is limited by the Employee Retirement Income Security Act of 1974 (ERISA).[1] ERISA preempts all state laws (including legislative enactments, administrative rulings, and judicial proceedings) that "relate to" employee benefits plans—that is, almost all private coverage except government and church plans and individually purchased insurance. ERISA allows states to continue to reg-

ulate insurance products but not employee benefits plans. States have no regulatory levers over benefits design or administration of groups that self-insure. The existence of ERISA makes patient protection in private insurance a federal issue as well as a state one. Federal oversight is also implicated for federal programs—notably Medicaid and Medicare, the Federal Employee Health Benefits Program (FEHBP), and military-related programs.

Patient Protection Provisions

Some of managed care's differences from traditional insurance have become concerns for many consumers, health care providers, and policymakers. Patient protection measures seek to address four main sources of fear about managed care: (1) the use of provider networks, (2) restrictions on benefits, (3) utilization management techniques, and (4) financial incentives to providers and patients.

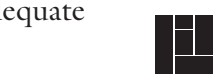
Limited Provider Networks

Networks are limited groups of providers, selected by an MCO, that enrollees must use to receive full payment for covered services. MCOs limit the number and types of participating providers for many reasons. Coordination of care is simpler among fewer physicians, and MCOs can select providers with compatible practice styles. In addition, a defined and limited membership allows MCOs to estimate a likely volume of patients for each provider and to negotiate service price discounts based on this expected volume. Furthermore, MCOs can impose treatment guidelines and administrative rules on network providers in a way that indemnity insurance cannot. Without the ability to contract selectively, necessarily excluding some providers, managed care would find it very difficult to effect the changes in medical spending and practice that large employers, governments, and other premium payers demand (GAO 1997a, Christianson 1998).

On the other hand, selective networks limit patient choice among providers at the time of service. An enrollee may not be able to visit a favored hospital or family doctor if the hospital or doctor is not included in the MCO network. Also, providers may leave or be "deselected" from networks, disrupting the provider-patient relationship. Further, if an enrollee develops a rare condition, there is a chance that preeminent specialists in that field will not be on the MCO's provider list. To visit these specialists, the enrollee would have to pay for the visit out-of-pocket, potentially a major barrier to access. Thus, providers and patients fear the limitation of choice inherent in the use of provider networks.

In response to these concerns, state and federal legislative proposals include such measures as:

- ***Network adequacy standards***—These require MCOs to maintain an acceptable ratio of providers to enrollees. There may be set rules, such as having one primary care physician within 30 minutes or 30 miles of every enrollee, or looser requirements, such as showing or being able to show that networks are adequate to handle the needs of the enrollee population.



- ***Access to out-of-network care if network is inadequate***—An extension of the previous requirement, this provision allows enrollees to visit out-of-network providers if no appropriate participating specialist is available in a timely fashion.
- ***Point of Service (POS) options or Freedom of Choice (FOC) requirements***—These require MCOs to permit enrollees to access out-of-network health care providers by requiring some level of coverage for out-of-network use.
- ***Continuity of care requirements***—These permit enrollees to continue their care with a health care provider for some transitional period if the provider leaves the network. Patients typically must have special conditions, such as pregnancy or chronic illness, to exercise this privilege.
- ***Rules for provider selection or termination***—These include a range of measures that govern the formation of networks, such as requiring public disclosure of selection criteria, written explanations to providers of reasons for nonselection or termination, and restrictions on the factors MCOs may consider in selecting network providers. An extreme version is an *any willing provider (AWP) law,* which requires MCOs to allow any provider who is willing to accept an MCO's terms and conditions to be included in a network.

Other measures aimed at controlling the use of networks are less often seen or have less practical impact. These include requirements for access to alternative providers, such as naturopaths or acupuncturists, and clauses that prohibit discrimination among providers on the basis of various characteristics. The latter do not typically prohibit selective contracting.

Benefits

Managed care organizations may also restrict the scope of benefits covered or limit access to covered benefits in the search for greater efficiency. Among these practices are limits on lengths of hospital stay, restricted coverage of emergency services, exclusion of experimental treatments, and the use of drug formularies. Out of concern that MCOs' incentives to reduce costs will lead them to deny access to important services, legislation may require that specific benefits be provided. Among the typical provisions are:

- ***Emergency room (ER) coverage provisions***—These require coverage of stabilization (and sometimes further service) for reasonable visits to the emergency room—for example, when a "prudent layperson" would think she required emergency treatment. The measures ban prior authorization for emergency services, and some require payment to emergency facilities outside the MCO's network.
- ***Access to clinical trials or experimental treatments***—These rules require MCOs to cover routine costs of an enrollee's participation in clinical trials or coverage for experimental treatments.
- ***Breast cancer hospital stays***—Similar to recent laws requiring MCOs to cover a minimum length of hospital stay for maternity care, provisions currently under consideration permit physicians and patients to determine length of stay for

breast cancer surgeries. Some also require coverage of reconstruction after mastectomy.

- ***Requirements for public disclosure of MCO terms and coverage***—These inform consumers about MCO benefits coverage, limitations, and sometimes utilization review procedures at the time of enrollment in the MCO.

Utilization Management

Another target of managed care regulation is MCOs' utilization management (UM). UM techniques include the procedures required to access covered benefits, how service delivery is reviewed and controlled, and how enrollees may appeal coverage denials. MCOs use a much broader range of UM strategies than indemnity insurers, often including gatekeepers—primary care physicians (PCPs) who act as case managers and determine when enrollees should be referred for specialist care. Other UM techniques include requiring preauthorization for expensive procedures or care, reviewing services for medical necessity, requiring adherence to standard treatment protocols, and setting organizationwide targets for service utilization.

Such UM techniques help MCOs reduce costs by limiting the inappropriate use of services, but opponents note that these rules restrict enrollee access to specialist services. For their part, providers often feel that MCOs' management of care conflicts with their own autonomy, especially if they feel that MCO guidelines represent an inadequate level of care. Some physicians have charged that MCOs have forbidden the discussion of uncovered treatment options with patients, but a U.S. General Accounting Office (GAO) report found no such "gag" clauses in the contracts it reviewed (GAO 1997b). Another issue is whether MCOs should be able to determine medical necessity, as they often do now under insurance contracts, or whether an external standard should be imposed, such as "accepted medical practice."

Policymakers want to ensure that MCOs do not act arbitrarily in denying services and that enrollees have recourse if benefits are inappropriately delayed or denied. Proposals addressing concerns about care management techniques cover a broad range of provisions, including the following:

- ***Noninterference rules***—These provisions prohibit MCOs from arbitrarily interfering with or altering the treating physician's decisions if ordered services are "medically necessary," a standard of coverage that is normally determined by the MCO.
- ***Explicit definitions of medical necessity***—Some managed care regulation defines medical necessity as being determined by accepted medical practice. Some construe these definitions to give attending physicians the power to decide what is medically necessary, rather than MCOs.
- ***Bans on gag clauses***—These disallow contract clauses that restrict physicians' discussions of all medically appropriate treatment options, including uncovered options, with enrollees.
- ***Within-MCO access provisions***—These allow enrollees in gatekeeper MCOs to visit specialists without obtaining a referral from a PCP first. Variations of these laws allow patients to designate a specialist as a PCP or to create "standing refer-

rals," which permit patients with qualifying conditions to receive ongoing treatment from a specialist.

- ***MCO liability***—This grants enrollees the right to sue their MCOs for personal injury due to coverage denials or other MCO decisions. Variations of this provision include malpractice liability reform and bans on requirements in physician contracts that MCOs be "held harmless" in any tort action.
- ***Enrollee appeals processes***—These require MCOs to permit enrollees to appeal coverage decisions, often both within the organization and to an independent external reviewer, whose recommendations may or may not be binding on the parties. Appeals processes may also set timelines for coverage decisions.
- ***Access to medical records and confidentiality***—These provisions require MCOs to have procedures for protecting the confidentiality of patient records. Some include procedures to allow patients to amend their medical files. Laws vary in specificity.
- ***Prohibitions on genetic discrimination***—MCOs may not require enrollees to reveal genetic information or use genetic information for underwriting purposes.
- ***Formulary opt-out***—This creates a procedure whereby patients can obtain drugs that are not on the MCO formulary if a nonformulary drug is medically appropriate.
- ***Utilization review requirements***—These set rules for internal utilization management procedures, often requiring that physicians be involved in setting all protocols/policies.
- ***Quality assurance requirements***—These require the establishment of internal quality assurance and improvement processes. Sometimes reporting requirements are included.

Many other UM provisions are less prevalent or less directly relevant to patient care. Examples include written policies for advance directives or organ donation or timelines for provider payment. Still other measures duplicate or amplify existing law, such as requirements for MCO solvency and certification or provider credentialing.

Financial Incentives

Some observers advocate regulation because managed care relies on financial incentives to patients and providers to encourage cost-effective behavior. For example, MCOs often charge enrollees a copayment for services or pay lesser amounts for out-of-network services. Some provisions restrict MCO payment differentials for out-of-network care or prohibit enrollee penalties for using other services, such as direct specialist access or ER care.

More consequential are the financial incentives that MCOs use to influence provider behavior. For example, most managed care organizations pay discounted fees to providers, as mentioned above. Some also use bonuses or "withholds" to reward success or penalize failure to meet utilization targets set by the MCO. Other MCOs use capitation, a flat per member per month fee, paid prospectively to providers to cover some or all services to enrollees. All of these incentives put providers

at some risk for high costs, which encourages them to moderate utilization, specialist referrals, or both. These incentives thus save money for MCOs and insurance consumers but raise concern that physicians may sometimes sacrifice quality of care to protect themselves financially.

Policymakers have enacted or considered a range of measures to address financial incentives in MCOs, including the following:

- ***Bans on the use of provider financial incentives*—**These prohibit MCOs from using specified (sometimes called "improper") financial incentives to encourage physicians to delay or deny services.
- ***Bans on gag clauses regarding financial aspects of MCOs*—**These prevent MCOs from requiring that physicians not discuss the incentive structure of the MCOs with patients.
- ***Public disclosure of financial incentives*—**This requires MCOs to inform consumers of the financial incentives used by the MCO at the time of enrollment or prohibits MCOs from preventing physicians from discussing financial incentives.
- ***Prohibition of the use of enrollee financial incentives*—**These are usually tied to other patient protections. For example, "direct access" provisions typically permit no penalties for taking advantage of direct access to specialists.

Federal Responses

The federal government has taken action to regulate managed care through executive and legislative action. The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry recommended a national Patients' Bill of Rights in November 1997, which included disclosure, access to emergency care, enrollee grievance and appeals processes, confidentiality of medical records, patient participation in treatment decisions, and choice of providers and insurers (Advisory Commission 1997, Stauffer 1999a). The president required all federal health plans to implement the commission's recommendations. These include the Medicare and Medicaid programs (although these programs were already substantially in compliance with the commission's standards), the FEHBP, the Indian Health Service, the Department of Defense Military Health Program, and the Veterans' Health Program (White House 1998). Together, these federal health programs cover an estimated 85 million Americans. In addition, the Department of Labor (DOL) was instructed to use its limited authority under ERISA to require private employee benefit plans, both self- and fully insured, to disclose adequate information and to strengthen MCOs' internal appeals processes (White House 1998). These ERISA-governed group plans are believed to cover 125 million Americans. Among ERISA plans, those that self-insure are not subject to any state insurance regulation. Sources suggest that self-insured employer benefits plans cover 48 million people in the United States (BNA 1999b).

In the legislative arena, the Balanced Budget Act of 1997 codified patient protection measures for Medicare and Medicaid clients. Implementing regulations were

proposed in September 1998, but final regulations have not yet been promulgated. Congress also has debated managed care consumer protection requirements for private populations. Some single-issue laws have been enacted, including a mandated length of stay for childbirth, but none of the more comprehensive consumer protection proposals have been enacted to date.

Pending Federal Proposals

Among the comprehensive federal patient protection proposals now under consideration (see table 1), there are four front-runners:

Table 1 *Managed Care Consumer Protection Bills in the 106th Congress*

	House				Senate				
	Democrat	Republican			Democrat		Republican		Bipartisan
Comprehensive patient protection bill	Dingell, H.R. 358	Bilirakis, H.R. 448	Norwood, H.R. 216	Ganske, H.R. 719	Daschle/ Kennedy, S. 6/240	Reed, S. 636 (children only)	Jeffords, S. 326	Lott/ Nickles, S. 300	Chafee/ Graham S. 374
Ombudsman program for health insurance consumers					Reed, S. 496				
Access to clinical trials only							Snowe, S. 117		
Breast cancer only	DeLauro, H.R. 116	Kelly, H.R. 383					Snowe, S. 115		
Equity in women's health					Schumer S. 479				
Whistleblower protection / Ban on retaliation for patient advocacy		Foley, H.R. 137			Wellstone/ Kennedy, S. 652				
Physician determination of hospital length of stay (all conditions)		Coburn, H.R. 989			Feinstein, S. 265/ 794				
Reconstructive surgery (all medical conditions)					Feinstein, S. 585				
Access to emergency medical services only					Graham, S. 517				
Prohibition of genetic discrimination							Snowe, S. 543		
Privacy of medical records	Markey, H.R. 1057				Leahy, S. 573		Jeffords, S. 578		
Outcomes research and disclosure							Frist, S. 580		

Source: http://www.thomas.loc.gov, accessed February 1999.

- A Democratic measure that takes the same form in both the House and the Senate (H.R. 358—sponsored by Rep. John Dingell; S. 6—Sen. Thomas Daschle),
- A bipartisan Senate bill (S. 374—Sens. John Chafee and Robert Graham),
- A House Republican bill (H.R. 448—Rep. Michael Bilirakis), and
- A Senate Republican bill (S. 326—Sen. James Jeffords).

The Jeffords bill is the only one to have advanced past committee, on a party-line vote, as of March 1999 (BNA 1999b).

Application

One of the biggest differences in the Republican, Democratic, and bipartisan approaches is the population each seeks to protect (see table 2). The bipartisan and Democratic measures have the broadest application, regulating both private employer health benefits plans and health insurance issuers, for both group and individual policies. ("Issuers" are what states often call "carriers," that is, state-licensed insurers, including Blues plans and health maintenance organizations (HMOs).) These plans and issuers are estimated to cover about 160 million Americans (Carey 1998, BNA 1999b). The House Republican proposal has a slightly narrower application, regulating private employer group health benefits plans and their health insurance issuers, but not individual products, already subject to state law. The bill would cover about 125 million people (Carey 1998). Finally, the Senate Republican bill would have the narrowest application. Most of its provisions regulate only those employer benefits plans that self-insure (48 million people), but it does extend the rules for independent external review processes to the fully insured population (Carey 1998, BNA 1999a).[2]

All bills create a national minimum standard or floor, supplemented by existing state rules. The bills would not preempt state statutes unless the state laws conflict with the federal legislation. States could impose more stringent rules (though only for insured products, not for employee benefits plans). The Senate Republican bill, which primarily applies to self-insured employee benefits plans, does not raise any issues of preemption of state law since self-insured firms are not subject to state insurance regulation. One reason Senate Republicans sought to regulate only self-insured plans was to make it clear that only the federal government would enforce any federal patient protection standards (BNA 1999a).

Substantive Provisions

Table 3 lists the major patient protection provisions included in the four bills mentioned above.[3] It also shows the number of states that have enacted similar provisions, according to various secondary sources. All of the bills provide access to the emergency room; disclosure of benefits, procedures, and provider and quality information; bans on gag clauses; direct access to obstetricians and gynecologists (OB-GYNs); internal appeals and independent external review processes; and bans on financially penalizing enrollees for taking advantage of specific protections. The bills

Table 2 *Application and Enforcement of Comprehensive Consumer Protection Bills under Consideration in the 106th Congress*

Bill	Amends?	Regulates?	Preemption of State Law?	Enforcement by?
Dingell/ Daschle H.R. 358/ S. 6[a,b]	● Public Health Service Act (PHSA) ● ERISA ● IRS Code	● Employer health benefits plans and health insurance issuers, covering an estimated *160–161 million* Americans with private health insurance. ● Covers enrollees in group health plans and those with individual coverage.	● Supersedes state law only where state law would prevent the application of a requirement of this act. ● Breast cancer treatment provisions do not preempt state law if state laws fit definitions specified in Act.	● Secretaries of Health and Human Services, Labor, and Treasury (issue regulations) ● States ● President/Congress (appoint Health Care Advisory Board) ● Institutional health care providers (post protections for patient advocacy)
Chafee/ Graham S. 374[c]	● PHSA ● ERISA ● IRS Code	● Employer health benefits plans and health insurance issuers, covering an estimated *160–161 million* Americans with private health insurance. ● Covers enrollees in group health plans and those with individual coverage.	● Supersedes state law only where state law would prevent the application of a requirement of this act. ● State may establish any requirement or standard that uses a shorter period of time for any internal or external appeals process.	● Secretaries of Health and Human Services, Labor, and Treasury (issue regulations) ● Director of Agency for Health Care Policy and Research ● States
Jeffords/ Lott/ Nickles S. 326/ S. 300[d,e]	● PHSA ● ERISA	● Self-insured employer health benefits plans, covering an estimated *48 million* Americans.[e] ● Most provisions apply to group benefits only. ● Some sections also apply to health insurance issuers (including information disclosure, grievance, and coverage appeals). ● Requirements for confidentiality apply to providers, health plans, health oversight agencies, public health authorities, employers, health or life insurers, health researchers, schools, universities, and law enforcement officials. ● Prohibition on genetic discrimination applies to individual policies as well as group policies.	● Bill applies only to self-insured health plans; no overlap with state law.	● Secretary of DHHS (issue regulations) ● Attorney General (consult with Secretary of DHHS in imposing civil monetary penalties)
Bilirakis H.R. 448[f,g]	● PHSA ● ERISA ● IRS Code	● Employer health benefits plans and health insurance issuers, covering an estimated *123–125 million* Americans. ● Group benefits only. ● Health care lawsuit reform title applies to actions against health care providers, any health benefit plan (including group health plans, issuers, third-party administrator (TPA), and Medicare+Choice plans), and manufacturers, distributors, suppliers, marketers, promoters, or sellers of a medical product.	● Preemption of state law where in conflict or where it is less stringent. (Specified only in sections on Association Health Plans, Health Marts, and Community Health Organizations.)	● Secretaries of Labor, Treasury, and Health and Human Services (issue regulations)

Sources: a. Daschle 1999; b. Carey 1998; c. Chafee 1999; d. Jeffords 1999; e. BNA 1999a; f. Bilirakis 1999; g. BNA 1999b.

differ in the general philosophy and range of other provisions, however. The Democratic bill takes the most restrictive approach, including controversial measures allowing enrollees to sue their MCOs or benefits plans (under limited circum-

stances), defining medical necessity, prohibiting "arbitrary" interference with physician decisions, and banning inappropriate financial incentives to physicians.

The Republican bills seek to avoid the more "costly mandates that could raise premiums and force people to lose coverage," mentioned above (BNA 1999b). Nor do they ban any prohibition of discussions of financial incentives between physicians and patients. They do allow patients to access and amend their medical records, a provision not seen in the bipartisan and Democratic bills. Beyond these commonalities, however, the two Republican bills are quite different from each other. The House bill, sponsored by Rep. Bilirakis, does not include the measures for continuity of care, confidentiality, or disclosure of physician financial incentives that are part of the Jeffords bill. The House bill does include a unique section creating new standards for health care liability lawsuits but no new ability to sue. The Senate Republican bill is the only one that prohibits issuers and plans from using genetic information to set premiums or exclude individuals from coverage.

The bipartisan bill seeks the middle ground: it duplicates most of the provisions in the Democratic bill, but importantly omits the enrollee right to sue plans or issuers, strongly opposed by Republicans, and includes direct access to pediatricians, strongly favored by Republicans. Oddly, while all three other bills require the offer of a POS option, the bipartisan bill does not. It also includes a provision not seen in other bills, protecting the mentally ill from involuntary disenrollment based on uncontrollable or abusive behavior.

Even where all the bills include the same provisions, however, the Democratic, Republican, and bipartisan approaches are often quite different in the details. For example, all grant enrollees the right to appeal plan coverage decisions to an independent external reviewer. Republican bills allow health plans to choose the reviewers, while the Democratic and bipartisan bills require external reviewers to be certified by the state or a federal Department of Health and Human Services secretary (DHHS), DOL, or Treasury. The Democratic bill allows appeals of any grievance, while the Republican measures permit review only of denials based on medical necessity or experimental treatment. Both Republican bills also constrain the evidence that outside reviewers may consider on appeal. The Senate bill has been amended to allow external reviewers to review the medical evidence of patients and physicians in addition to a plan's clinical practice guidelines, but it does not allow complete *de novo* review of the entire case, as in the Democratic bill (BNA 1999b). The House Republican bill, unlike the other bills, requires the enrollee to pay for the review but does not require employee benefits plans or health insurance issuers to follow the reviewer's recommendations.[4] In contrast, the Democratic and bipartisan measures require the health plan or issuer to pay the costs of the process. In short, even where bills have the same provisions, the specifics differ enormously.

If no agreement can be reached on a comprehensive bill, one possible compromise would be a "lean" bill embodying the most broadly accepted provisions—those that do not greatly raise costs or challenge the most fundamental aspects of managed care. Such compromises have helped states break legislative deadlocks over controversial provisions such as the right to sue, sweeping prohibitions of financial incentives, or broad requirements of clinical autonomy over what constitutes "medically necessary" care (AHL 1999). Last year's House Republican bill (H.R. 4250), the

Table 3 *Managed Care Patient Protection Provisions in Federal Bills, 106th Congress*

Provision		Democratic: Dingell/Daschle H.R. 358/S. 6[a]	Bipartisan: Chafee/Graham S. 374[b]	Republican: Jeffords/Lott S. 326/S. 300[c,d]	Republican: Bilirakis H.R. 448[e]	Number of States (Approximations)
Network Formation						
Network access standards		X	X			20[f]
Access to out-of-network care if network is inadequate		X	X			15[g]
POS option		X		X	X	17[h]–18[i]
Continuity of care		X	X	X		21[i]
Provider selection/ Termination rules	Written notice of contract termination or nonselection	X	X			24[k]
	Provider appeals process	X	X			11[i]–17[k]
	Disclosure of selection criteria	X	X			17[k]
	Specified terms of provider selection/nondiscrimination	X	X			n/a*
	Any willing provider					24[i]
Benefits Coverage and Limitations						
ER access		X	X	X	X	43[l]
Access to clinical trials		X	X			3[g]
Hospital stay for breast cancer surgeries		X	X			18[i]
Disclosure		X	X	X	X	at least 27[f]
Utilization Management						
No arbitrary interference with physician treatment decisions		X	X			n/a
Medical necessity defined as consistent with accepted professional medical practice		X	X			3[m]
Ban on gag clauses		X	X	X	X	47[n]
Access within network	Specialists as PCPs	X	X	X		10[g]
	Direct access to OB-GYNs	X	X	X	X	31[g]
	Direct access to pediatricians		X	X	X	n/a
	Standing referrals	X	X			13[g]
Health plan liability	Enrollee right to sue	X				2[g]
	Uniform standards for health care liability lawsuits				X	n/a
	Prohibition of indemnification (hold harmless) clauses	X	X			16[o]
Coverage decision timeframes and written notice requirements			X	X	X	at least 3[f]
Internal appeals rules		X	X	X	X	50[p]
Independent external review		X	X	X	X	22[i]
Patient access to medical records, procedures for amendment				X	X	n/a

(continued on next page)

Table 3 *Managed Care Patient Protection Provisions in Federal Bills, 106th Congress, continued*

Provision	Democratic	Bipartisan	Republican		Number of States (Approximations)
	Dingell/Daschle H.R. 358/S. 6[a]	Chafee/Graham S. 374[b]	Jeffords/Lott S. 326/S. 300[c,d]	Bilirakis H.R. 448[e]	
Utilization Management, *continued*					
Medical record confidentiality	X	X	X		at least 12[f]
Prohibition of genetic discrimination			X		27[q]
Procedures to obtain nonformulary drugs	X	X	X		8[g]
Requirements for utilization review procedures	X	X			at least 19[f]
Mandated quality assurance and improvement programs	X	X			at least 11[i]
Financial Incentives					
Prohibition on financial incentives to deny care	X	X			24[r]
Bans on clauses preventing physicians from discussing financial terms of plan with patients	X				8[i,s]
Disclosure of compensation methods	X	X	X		6[i]
No enrollee financial incentives for certain services	X	X	X	X	13[i,s]
Other Provisions					
Consumer assistance program	X	X			3[g]
No involuntary disenrollment due to mental illness		X			n/a
Nondiscrimination against enrollees in delivery of services	X	X			n/a
Reformation of Agency for Health Care Policy and Research (AHCPR) as Agency for Healthcare Research and Quality (AHRQ)			X		0
Required study by DHHS, Institute of Medicine (IOM), AHRQ, and National Institutes of Health (NIH) of all future proposed benefits mandates			X		0
Creation of National Health Care Advisory Board	X				0

Sources: a. Daschle 1999; b. Chafee 1999; c. Jeffords 1999; d. BNA 1999b; e. Bilirakis 1999; f. Stauffer 1999a; g. Families USA 1998; h. Stauffer 1999f; i. Laudicina et al. 1998b; j. Stauffer 1999i; k. Stauffer 1999g; l. Stauffer 1999e; m. Stauffer 1999h; n. Stauffer 1999d; o. Rothouse 1999; p. Stauffer 1999b; q. Herstek 1999; r. Stauffer 1999c; s. Laudicina et al. 1998a.

*n/a means not available. States may have such provisions, but no secondary source has catalogued such requirements.

only bill to pass either chamber, may hint at what a successful compromise bill could include: mandatory offer of a POS option, disclosure requirements, a ban on gag clauses, access to emergency room care, continuity-of-care provisions for pregnant women, standards for internal appeals, provisions for independent external appeals, and medical record confidentiality rules.

What Federal Legislation Means for States

The legal application and content of federal bills just discussed are very important in understanding how any enactment would affect the states. Practical impacts

in any given state also depend on how many residents are in managed care but have little or no patient protection under existing state or federal rules. This section addresses state-by-state variations in impact depending on the size of each state's affected populations and the extent of existing state protections. The 13 ANF focus states[5] illustrate the wide variation in both these factors.

Size of the Affected Population

Some residents in every state are already covered by managed care consumer protections under federal government–sponsored health plans. Also, in some states, only a small percentage of the population is covered by self-insured health benefits plans, expanding the reach of any existing state regulation. The importance of federal patient protection legislation depends in part on how many people in the state are enrolled in managed care plans, the target of most patient protection standards. So in a given state, the number of people affected by new federal legislation would depend in part on the extent of coverage in federal plans, self-insurance, and managed care penetration.

Federal plan coverage

A substantial portion of people in every state are already covered by patient protection requirements under federal health programs. Medicare, FEHBP, and military and veterans' programs insure about 15 to 20 percent of residents in each of the 13 focus states (U.S. Bureau of the Census 1998).[6] There is even greater variation across the 13 focus states in Medicaid enrollment, ranging from 5.9 to 18.1 percent of the nonelderly population in Colorado and California, respectively (Liska et al. 1998).

Self-insurance

The fewest legal protections apply to the self-insured, so it is of great interest to know the extent of self-insurance by state. Unfortunately, there are no state-level estimates for the number of people covered by self-insured health benefits plans, but the figure surely varies by state.[7]

MCO penetration

A more measurable portion of the state population likely to be affected is the percentage covered by managed care organizations. Where few residents are served by MCOs, legislation limiting MCO practices would affect care for only those few. Note that low MCO penetration does not always correspond with low levels of state managed care regulation.

Table 4 shows the penetration of health maintenance organizations and preferred provider organizations (PPOs) in the 13 focus states.[8] California, Colorado, and Minnesota have high rates of both HMO and PPO penetration relative to other focus states. Thus, these states would feel the largest impact of new federal managed care legislation, other things equal. The smallest impact would occur in states with relatively low enrollment in both HMOs and PPOs, like Mississippi and Michigan.

Table 4 *Managed Care Penetration in 13 States*

State	HMO Penetration, 1996[a] (percent of total population)	In-State PPO Penetration, 1994[b] (percent of total population)
United States	24.0	N/A*
Alabama	8.6	34.5
California	42.6	23.4
Colorado	28.3	50.9
Florida	26.3	22.2
Massachusetts	39.3	7.6
Michigan	23.2	7.7
Minnesota	31.5	32.9
Mississippi	1.9	22.8
New Jersey	26.7	13.1
New York	30.9	3.8
Texas	13.2	28.7
Washington	21.1	24.1
Wisconsin	29.4	11.2

Sources: a. Interstudy 1997; b. HIAA 1995.

* Not available. Health Insurance Association of America (HIAA) included enrollment in national PPOs in the U.S. total but omitted enrollment in multistate PPOs from state figures. For that reason, the national and state numbers are not comparable.

Several other states have high percentages in HMOs but not PPOs (such as Massachusetts) or vice versa (for example, Texas). Such disparity in penetration rates may occur where one type of health plan enjoys regulatory advantages or became entrenched before other plan types developed. New regulation will have considerable effects if it targets the type of managed care with the largest enrollment but only marginal effects if it targets a plan type with small statewide enrollment. Where regulations apply to all forms of health insurance, the impact on the state will still be influenced by managed care penetration, because managed care practices will be more widespread (even among traditional forms of insurance) where MCOs have high market share.

The specific requirements enacted will also be more relevant to some forms of health insurance than to others. In general, patient protection provisions would be expected to affect indemnity plans the least, HMOs the most, and PPOs somewhere in between; but this depends on the mix of controls used by a given MCO. For example, since there are no networks and no gatekeepers in indemnity insurance, provisions like direct access to specialists, the option to use out-of-network providers, and continuity of care would be irrelevant to indemnity carriers. Most PPOs do not use gatekeepers but do have a limited provider network, so some network restrictions would apply. However, PPOs already provide partial coverage for out-of-network services, so a mandated POS option would be superfluous. Mandated POS and continuity of care might be most onerous for staff-model HMOs, which rely on a relatively small, closed panel of physician employees. HMOs that capitate physician groups globally for all services might be little affected by UM restrictions but would have big problems with restrictions on financial incentives. To the extent that HMOs are most apt to use all of these types of controls, they would be most affected by patient protection regulation.

Existing State Regulation

The likely effect of federal patient protection legislation also depends on the extent to which states have already enacted similar statutes. Duplicative federal legislation would not make substantial changes. Indeed, if federal legislation delegates enforcement authority to states (as discussed below), nothing would change. The exceptions to this, of course, are that federal statutes may preempt conflicting state requirements and that they can protect more insured people than state regulation can. The provisions under consideration at the federal level were generally enacted first at the state level, so they tend to be similar to the managed care rules seen at the state level. However, the details of some provisions, such as the appeals timetable, often vary across states and between the states and the federal proposals.

Table 5 shows the key provisions in the 13 focus states and the total number of provisions each state has in force. The types and numbers of provisions enacted vary greatly across the selected states (this is also true for the rest of the states not shown here). A few provisions in proposed federal legislation would be totally new to every state because no state has them, including rules requiring direct access to pediatricians and noninterference with physician decisions. Other measures have been enacted in only a few states, including an enrollee right to sue health plans (Texas and Missouri), definitions of medical necessity (North Dakota, Georgia, and Texas), and access to clinical trials (Georgia, Maryland, and Rhode Island) (Stauffer 1999h, Families USA 1998). A few state measures would be wholly unaffected by the legislative proposals we studied because they have no federal counterpart, including AWP laws and others not included in Table 5. The four bills we studied would not make managed care regulation completely uniform across states but would generally create a floor of minimum standards.

Certain measures have been widely enacted across states. The ban on gag clauses has achieved near unanimity, even though in practice gag clauses appear to be rare (GAO 1997b). Other widely enacted measures are direct access to OB-GYNs, access to emergency services, and disclosure of plan information at the time of enrollment. These provisions may evince either the most widely shared fears about managed care or, alternatively, the simplest points of consensus.

Seven of the 13 states have high counts of managed care patient protection provisions.[9] Texas, New York, and New Jersey have the largest number of restrictions, at 21, 18, and 17, respectively. Other things equal, these states would see the least impact from the federal legislation, although state law might have to be harmonized with specific provisions of federal law. Among the six focus states with low numbers of managed care provisions are Washington, Massachusetts, and Alabama, with only 5, 6, and 6 already in force. These states would see the greatest impact from a federal law.

Because of the split in regulatory authority over fully insured vs. self-insured employee benefits plans, after any federal enactment, protections for residents within any one state might be uniform or might still vary by insurance status. Under the Democratic and bipartisan federal bills, protections for a given state's residents would be uniform in states that previously had the same or fewer enacted protections, because the minimum floor of federal legislation would set a new state maximum.

Table 5 *Managed Care Patient Protection Provisions in the 13 Focus States*

Provision		AL	CA	CO	FL	MA	MI	MN	MS	NJ	NY	TX	WA	WI
Network Formation														
Network access standards*,†[a,b]				X	X			X			X	X		
Access to out-of-network care if network is inadequate[c]				X	X						X	X		
POS or FOC option[d,e]		FOC			FOC		POS	POS	FOC	both	POS	both		
Continuity of care[f]			X	X	X			X		X	X	X		X
Provider selection/ Termination rules	Written notice of contract termination or nonselection[g]		X	X	X		X			X	X	X		
	Provider appeals process[g]			X					X	X	X	X		
	Disclosure of selection criteria[g,h]		X				X		X		X	X		X
	Set terms of provider selection/nondiscrimination	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Any willing provider[b,i]	X^			X	X		X	X	X		X		X
Benefits Coverage and Limitations														
ER access[b,c,j]		X	X	X		X	X		X	X	X	X	X	
Access to clinical trials[c]														
Hospital stay for breast cancer surgeries[k,l]			X		X					X	X			
Disclosure*[a,b]		X	X	X		X	X		X	X	X	X		
Utilization Management														
Noninterference with physician decisions		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Medical necessity—consistent with accepted professional medical practice												X**		
Ban on gag clauses[c,m]			X	X	X	X	X	X		X	X	X	X	
Access within network	Specialists as PCPs[a,b,c]	X							X	X	X	X		
	Direct access to OB-GYNs[a,b,c]	X	X	X	X			X	X	X	X	X	X	
	Direct access to pediatricians	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Standing referrals[a,b,c]		X		X			X			X			X
Health plan liability	Enrollee right to sue plan for damages[c,n]											X		
	Uniform standards for health care liability lawsuits	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Prohibition of indemnification (hold harmless) clauses[n]										X	X+	study	
Coverage decision timeframes and written notice requirements*[a]														
Internal appeals rules[o]		X	X	X	X	X	X	X	X	X	X	X	X	X
Independent external review[c,o]			X	X	X		X	X		X	X	X+		
Patient access to medical records, procedures for amendment		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Medical record confidentiality*[a]								X						
Prohibition of genetic discrimination[p]		X	X	X	++			X		X	++	X		X
Procedures to obtain nonformulary drugs[c]			X											
Requirements for utilization review procedures*[a]										X	X	X		
Mandated quality assurance and improvement programs[b]														X

(continued on next page)

Table 5 *Managed Care Patient Protection Provisions in the 13 Focus States, continued*

Provision	AL	CA	CO	FL	MA	MI	MN	MS	NJ	NY	TX	WA	WI
Financial Incentives													
Prohibition on financial incentives to deny care[c,q]		X		X			X		X		X		
Bans on clauses preventing physicians from discussing financial terms of plan[b]			X		X	X							
Disclosure of compensation methods[b]		X					X		X				
No enrollee financial incentives for certain services[b]			X	X	X			X					
Other Provisions													
Consumer assistance program[c]				X	X^^		X						
Count per state	**6**	**15**	**14**	**16**	**6**	**9**	**16**	**8**	**17**	**18**	**21**	**5**	**8**

Sources: a. Stauffer 1999a; b. Laudicina et al. 1998a; c. Families USA 1998; d. Stauffer 1998g; e. Stauffer 1998h; f. Stauffer 1998e; g. Stauffer 1999g; h. HPTS 1998; i. Stauffer 1998a; j. Stauffer 1998f; k. Kaiser 1998; l. Laudicina et al., 1998b; m. Stauffer 1998c; n. Rothouse 1999; o. Stauffer 1998i; p. Herstek 1999; q. Stauffer 1999c.

Notes:

* No source deals with these standards explicitly; therefore, we may have missed existing legislation in some states.

¶ UI ANF case studies.

^ Alabama's AWP law was ruled preempted by ERISA by a U.S. District Court.

**Texas defines medical necessity only to bar MCOs from retaliating against physicians who advocate for medically necessary care for their patients (sec. 888.002(f)).

+Texas's hold harmless and external appeals laws were overturned by the U.S. District Court for the Southern District of Texas.

++New York and Florida have laws requiring confidentiality of genetic testing but do not prohibit rate or coverage discrimination.

^ ^ By Executive Order.

n/a appears where we do not have evidence regarding individual state enactment of certain provisions.

However, states with greater regulation would have two tiers of protection—more for residents with fully insured coverage regulated by the state and only the federal minimum for the self-insured. Under the Senate Republican approach, nearly every state would have different levels of protection for different populations, because existing state rules would continue for the fully insured, and probably somewhat different national federal rules would apply to the self-insured. State insurance regulators, through the National Association of Insurance Commissioners, have urged Congress not to interfere with existing state regulations or to impose national uniformity, arguing that states are responsive to their own conditions (Sebelius 1999). They are thus perceived as supporting the Jeffords bill or a similar Republican proposal (AMN 1999).

Intersection of Regulation and Penetration

The influences of managed care penetration and existing state regulation interact. High-penetration states with few existing provisions would be greatly affected by new federal law. In contrast, low-penetration states with more existing regulation would see little change for the fully insured population. Tables 6a and 6b plot the intersection of managed care regulation and managed care penetration among the 13 focus states. With regard to HMO enrollment, Texas would probably be least affected by federal legislation because it has relatively low HMO penetration but

Table 6a *Managed Care Regulation and HMO Penetration in the 13 Focus States*

	Number of Provisions	
Percent in HMOs	Low	High
High	Massachusetts	California
Medium	Wisconsin Michigan Washington	Minnesota New York Colorado New Jersey Florida
Low	Alabama Mississippi	Texas

Table 6b *Managed Care Regulation and PPO Penetration in the 13 Focus States*

	Number of Provisions	
Percent in PPOs	Low	High
High	Alabama	Colorado Minnesota Texas
Medium	Washington Mississippi	California Florida
Low	Wisconsin Michigan Massachusetts	New Jersey New York

many patient protection measures. Among the 13 focus states, the greatest impact would theoretically come in Massachusetts, where HMO enrollment is relatively high and the number of provisions is low. Looking at PPO enrollment, Alabama would be likely to see the greatest impact from federal legislation, while New Jersey and New York would see little impact. As already mentioned, the extent of self-insurance would affect the calculus of practical impacts as well.

Implementation and Enforcement

The pending federal proposals take very different approaches to implementation and enforcement, which derive from the differences in the entities they target for regulation.[10] Differences follow partisan lines, as they do for the substantive rules already discussed. All current proposals build on the prior federal assignment of responsibilities under the Health Insurance Portability and Availability Act of 1996 (HIPAA). As a group, the federal proposals make use of two ways to enforce new law—through administrative oversight and through the provision of legal remedies for aggrieved individuals.

Administrative Oversight

For administrative oversight, HIPAA established a hierarchy of shared responsibilities, both within the federal level and between federal and state enforcement authorities. Arrangements are complex and can only be sketched here.[11] Federal responsibilities are split between the Departments of Labor and of Health and Human Services, with a smaller role for the Treasury Department, mainly to enforce some tax penalties. All the departments collaborate to develop substantive regulations to implement HIPAA, but implementation is parceled out: DOL oversees ERISA plans, namely workplace-based group benefits plans run by employers or unions. DHHS covers issuers of coverage, that is, state-regulated insurers. For such insurance products, Congress intended states to play a major role, and HIPAA calls for DHHS to delegate responsibility for enforcement to states where their laws are consistent with HIPAA rules (some states had to enact conforming amendments). Where state rules fall short of HIPAA requirements, DHHS regulates issuers directly; as of this writing, direct DHHS regulation applies in five states.

The Senate Republican bill on patient protection applies almost exclusively to coverage for self-insured, employment-based groups, which under ERISA are not subject to any state regulation. Requirements on appeals of benefit denials apply to all ERISA plans. To issue regulations and enforce requirements, the bills rely exclusively on DOL, which oversees ERISA. Enforcement powers include the ability to set limited civil monetary penalties. DOL has already applied some patient protection rules relating to disclosure for employment-based plans, as mentioned above (DOL 1998b). State rules are unaffected by the Senate Republican approach. It is possible that there will be some administrative coordination of activities between DOL and state authorities, although this is not explicitly provided in the bills.

The main Democratic bills follow the HIPAA model even more closely because they apply to all private coverage, as HIPAA did. Like HIPAA, they allow states to assume enforcement responsibility where they already have enacted or subsequently enact similar or stronger patient protections. Where states have not acted, DHHS is to enforce patient protections for plans buying fully insured coverage through rules on "issuers" of coverage. The bills do not specify who will judge whether states qualify for enforcement responsibility, but this will presumably be similar to the HIPAA process of state certification and DHHS review and approval.

For ERISA plans, notably including the self-insured, the Democratic proposals call for DOL to enforce the federal patient protections (just as the Republican one does).

The bipartisan proposal (S. 374) has the most developed enforcement provisions (Subtitle D—Enhanced Enforcement Authority). It gives DHHS the same authority to investigate violations as DOL has to enforce ERISA and allows DHHS to compel states that have assumed HIPAA responsibilities to explain their enforcement efforts relevant to patient protection (sect. 141(a)). The bill creates authority for the secretaries of DHHS and DOL to apply a graduated schedule of civil money penalties and new power to order injunctive relief.

The leading Senate Republican bill (S. 326) relies mainly on one general provision authorizing the secretary to impose a civil penalty on any party for "substantially and materially" violating the act (sec. 231(a)).[12] The secretary must consult with the attorney general in making this determination, and the procedures of Medicare enforcement apply (Social Security Act sec. 1128A). The House Republican counterpart (H.R. 448) goes further, authorizing fines up to $100,000 where violations are so frequent as to constitute a general business practice.

The leading Democratic bill (S. 6/H.R. 358) relies mainly on existing sanction authority. Under ERISA, various fines can be imposed on a daily basis for different kinds of violations.

Patient Protection and Lawsuits against Health Plans

Another highly controversial source of enforcement is expanding patients' ability to bring personal injury lawsuits against health benefits plans and health insurance issuers. Federal proposals have differed markedly in their treatment of lawsuits, with President Clinton and most Democrats supporting expanded claims for personal injury and most Republicans opposed or allowing only very structured remedies.

State law of personal injury and federal preemption of litigation

Today, although patients can readily sue a health care provider for malpractice under state law, they can seldom litigate claims that managers of care have caused personal injury (Table 7), for two main reasons. First, state judicial doctrines have not yet evolved to hold plans responsible for failures in medical care. State judicial doctrine traditionally held that plans do not practice medicine, hence they cannot be sued for malpractice. Similarly, the law traditionally viewed physicians and hospitals under most managed care arrangements as "independent contractors" for whose negligence the plans were not responsible (Rosoff 1987, Sage 1997). Judicial precedent has only just begun to evolve new theories of managerial liability (Bearden and Maedgen 1995).

Texas and Missouri in 1997 legislated new legal bases for claims against health plans (Butler 1997). The Missouri reform defines HMOs (but not other MCOs) as "medical providers" for purposes of tort "actions based on improper health care" (sect. 538.205). Thus, HMOs would be judged liable for malpractice by the same standards as clinicians. Plans would also benefit from legislative "tort reforms" that protect medical providers, notably including limits on damages. The Texas statute establishes liability for any "health insurance carrier, health maintenance organization, or other managed care entity" that fails to exercise "ordinary care" in making "treatment decisions" (Texas Code 1999, sect. 88.002(a)). The law calls for assessment of managed care behavior by managed care standards, not by medical standards (sect. 88.001 (10)), potentially a very important distinction (Bovbjerg 1975, Morreim 1997). Most state legislatures considered liability reforms in 1998 or 1999, but none has enacted them.

Table 7 *Consumers' Ability to Sue for Injury Caused by Health Plan Coverage Decisions*

Source of Coverage	Estimated Number of Americans Covered*	Available Remedies
State-regulated plans (individual market)	10–16 million	In most states, individuals can sue health plans in state courts either under contract law to claim denied benefits or under tort law for personal injury, to claim compensation for monetary and intangible losses as well as punitive damages.
State and local government employee plans	23 million	In most states, individuals can sue health plans in state courts under contract law for benefits or under tort for personal injury.
Medicaid (traditional or managed care)	37 million	Individuals cannot sue the federal government but can sue state Medicaid programs and health plans in state courts under either contract law or tort law for personal injury.
Medicare (traditional or managed care)	37 million	Individuals cannot sue the federal government but can sue health plans in state courts under either contract law or tort law.
Federal Employees Health Benefits Program (fully insured plans)	9 million	Individuals can sue either the Office of Personnel Management in federal court or a health plan in state or federal court. Remedies are limited to provision of the service denied, an injunction to order the plan to act, and clarification of future benefits.
ERISA-regulated plans (workplace group plans, both self-insured and fully insured, except government and church plans)	123 million (includes 76–92 million fully insured; 32–48 million self-insured)	Individuals cannot sue health plans in state courts. Suits can be brought in federal court, where remedies are limited to provision of the covered service at issue or the cost of that service, an injunction ordering the plan to act, and clarification of future benefits. (States may regulate insurers' benefit packages but not their dispute resolution.) Some courts have recently held plans responsible for provider negligence.

Source: Adapted from Advisory Commission (1998), chapter 10, table 1.

Note:
* Total may be higher than the number of insured Americans because of dual eligibility among the categories.

The second reason that litigation focuses on providers rather than plans is ERISA preemption. In the interest of national uniformity of benefits administration, ERISA creates an exclusive federal court remedy for resolving disputes about benefits under employee benefits plans (Sage 1997). ERISA preempts inconsistent state laws, including not merely insurance regulation of self-insured plans but also court-made tort law. An ERISA claim can recover only denied benefits plus reasonable attorneys' fees—not lost wages, pain and suffering, or punitive damages. Before the mid-1990s, courts interpreted ERISA very broadly, striking down many state actions that affected health benefits plans, notably including a claim for punitive damages against an ERISA insurer.[13] Since two landmark U.S. Supreme Court decisions upholding state health regulation,[14] courts have sometimes allowed personal injury lawsuits to proceed despite ERISA, especially with regard to quality of benefits (Rooney 1998).[15] Still, claims for direct negligence in benefits administration typically remain preempted (Sage 1997), and the main legal remedy available is an ERISA claim for lost benefits.

Federal Proposals

Expanding patients' ability to sue is one of the most contentious aspects of the federal debates over patient protection. Major differences in approach among

Republican, Democratic, and bipartisan proposals echo previous disputes over tort reform of many types. For Democrats, ensuring access to courts is a key enforcement tool, and ERISA preemption is an unjust roadblock that needs to be removed. Republicans tend to see litigation as slow, costly, and ineffective and ERISA protection as an appropriate shield for private purchasing of benefits (Collins 1999, Nickles 1999).

Accordingly, the main Republican patient protection bills would create no new federal right to sue health plans or other managers of care. The Jeffords bill (S. 326) recognizes the issue of error in medicine but calls for research and private-public partnerships to address the issue, not new legal remedies. Nor, on the other hand, do the Republican bills attempt to restrict state developments that are creating such rights, such as the Missouri and Texas statutes, as well as a growing body of judicial precedent.[16] One exception is H.R. 719 from Rep. Greg Ganske of Iowa, which would amend ERISA to allow lawsuits but would greatly restrict punitive damages.[17]

In sharp contrast, Democratic proposals would amend ERISA to remove impediments to personal injury lawsuits. The identical Daschle and Dingell bills remove the ERISA preemption of state lawsuits but exempt employers from liability unless they are exercising discretionary authority on a claim for benefits (S. 6, sect. 302(e), H.R. 358, sect. 713(3)). The intent seems to be to hold liable only those *directly* involved in utilization review or other similar influences on delivery of care.[18] These bills would leave all rules to be developed by state courts and state legislatures. Unlike the Missouri or Texas laws, the federal bills take no position on whether managed care should be judged by new managed care standards or by traditional concepts of medical negligence, on what damages are obtainable, or on any other aspect of liability law. They also provide that any other existing private rights to action are to survive.

The bipartisan proposal (S. 374) expands sanctions against group health plans under ERISA for injuries resulting from coverage determinations that are not timely or not made in accordance with terms of the plan. It allows recovery of "economic loss" (e.g., medical expenses, lost wages) in addition to the cost of the wrongfully denied benefits (sect. 302). By increasing the value of ERISA recoveries, this provision could make lawsuits more likely but would not change the basis of plan responsibility. A plan's obligations to patients would remain largely determined by its own terms.

Implications of Federal Law for States

The main Republican and bipartisan reforms would make little difference to states or to patients. For most Americans, the liability of their managers of care would still be determined mainly by court interpretations of ERISA. The Democratic proposals, however, would greatly accelerate the development of tort law by removing ERISA preemption of state law. States would be free to legislate, but the main engine of change would be the threat of litigation to enforce statutory patient protections and develop new bases of liability in court. What practical impacts would occur depends on the number and scope of new cases brought, the duties each state's courts develop for MCOs, and the responses from patients, providers, and managers of care. If any of the proposals are enacted as written, the liability provisions would

create no national uniformity whatsoever—unlike the other patient protection provisions. All rules would vary by state. This would be a major change for ERISA plans, although companies face exactly this sort of legal variability by state in other aspects of injury law, such as workers' compensation and products liability.

Conclusion

Patient protection has become an important legislative issue, first in states and now in competing federal proposals. Our comparative review of enactments and proposals, along with case-study information about 13 representative states, suggests four main conclusions.

First, all the main federal patient protection bills would apply to some populations not now reached by state rules. Most obviously, all the federal proposals would impose at least some standards on ERISA plans, that is, workplace-based employee benefit plans. States cannot regulate ERISA benefit plans directly and cannot even indirectly regulate those that self-insure. States can regulate only fully insured products, including HMOs and other risk-bearing managed care entities. The Senate Republican bills limit themselves almost exclusively to self-insured employer plans, whereas other proposals, including the House Republican, Democratic, and bipartisan bills, set minimum standards for fully insured coverage as well.

Second, how much difference any new rules make in their practical application depends on how much the new rules differ from existing rules and voluntary practice and on the extent of managed care within the affected population. Federal enrollees and beneficiaries nationwide, including Medicaid clients, would experience relatively little change. The Balanced Budget Act of 1997 and presidential Executive Orders in 1998 have already imposed many or most of the protections proposed in the federal bills. For private enrollees, employment groups and health plans are already implementing some protections voluntarily or through private certification programs (AAHP 1997, NCQA 1999). How much this has occurred is not ascertainable from available information. Moreover, in many states, managed care penetration remains low. In others, state regulation is already high. In such states, relatively fewer people would be affected by new federal provisions. Practical impact would be greatest in states where penetration is relatively high, yet regulation is low. Impact would be least where penetration is low and regulation high.

Third, the leading federal bills have very few wholly new substantive provisions. What is new is the comprehensiveness of the "package" of protections and the breadth of their proposed application. In other words, states developed the overall repertory of available methods of protection—rules on network formation, benefits coverage, utilization management, and financial incentives—but a federal law would make the enacted package of rules relatively comprehensive in all states for the targeted share of the population. Today, all states have some provisions, and half say they have a "patients' bill of rights," but it is rare for any single provision to have been enacted in most states. The count for most rules does rise each year, as states continue adding provisions.

Among the types of provisions, rules on benefits coverage and utilization management overlap most among the federal bills and between them and existing state laws. All the federal proposals have numerous such provisions, although the Republicans have somewhat fewer than the bipartisan, and the Democrats more. One major difference should be highlighted: The Democratic and bipartisan proposals would impose strong new requirements on how MCOs determine whether a service is "medically necessary" and hence contractually covered for payment. Such rules appear to be very rare at the state level. On its face, this would seem to be a major restraint on managed care operations.

On network formation and financial incentives, the federal proposals differ more from state practice, and there is greater variation among federal bills. Notably, as to networks, no federal bill includes an "any willing provider" requirement. AWP laws exist in about half the states, although some laws on the books have been invalidated in court under ERISA.

Finally, in terms of enforcement provisions, some of the federal proposals would significantly depart from existing state practice. All the bills include standards for internal and external appeals of payment denials. They differ in defining which denials are appealable; Democratic proposals are broader. In contrast, significantly less than half of states address appeals, although the trend is toward expansion of appeals rights, both in state legislatures and in private certification. The bills also confer some new powers on federal enforcement agencies, specifically the Departments of Labor and Health and Human Services. Even so, the federal enforcers still would not have the full panoply of "levers" over insured plans that are available to state insurance regulators and departments of health, notably including revocation of license. All the bills that regulate insured forms of managed care (the Senate Republican bill does not) would allow states to opt to enforce their own rules in place of a federal provision—so long as they provide at least substantially similar protections and are consistent with the corresponding federal rule.

The biggest enforcement change, and arguably the biggest change overall, would come from a new, open-ended right to sue for personal injury, normally under state law. The right to sue is a centerpiece of the main Democratic proposals but is omitted from bipartisan and Republican bills, as Republicans in general oppose expanded litigation. Democrats consider lawsuits an enforcement tool, but their bills' right to sue is not tied to violations of the rest of the bills' provisions. A patient losing an external appeal, for example, could take another shot at winning through litigation. (The bipartisan proposal allows restricted recoveries—under federal, not state, law—and the Ganske Republican bill proposed as a compromise would allow suits, subject to a ban on punitive awards when appeals procedures have been followed.)

A new right to sue managed care organizations would be a big change. Current law seldom imposes liability, and the federal administrative rules and the Balanced Budget Act stopped short of such change. Liability of managed care organizations will grow under any scenario, as courts are changing their interpretations, and two states have enacted facilitating statutes. But how quickly change will occur under current law and how far it can go are not clear. The Democratic proposals, in contrast, would immediately lift ERISA restraints on litigation nationwide.

Thus, almost all of the federal proposals look very familiar; many would not apply to indemnity or lightly managed care in many regions. Many of the proposed regulations would duplicate existing rights and remedies, yet all would extend new protections to many people, especially the self-insured and residents of states with few state provisions. Depending on the precise substantive provisions enacted, any federal bill could considerably alter the operations of health coverage nationwide.

Notes

1. ERISA is codified at 29 U.S.C. sect. 1101–1461 (1994).
2. It is unclear whether states can enforce external appeals laws because they are not directly related to health insurance. A recent ruling on Texas's patient protection laws held that its external appeals process was preempted by ERISA (BNA 1999b).
3. Several of the bills have additional measures that are not strictly patient protections and are thus not included here. These are mainly targeted at expanding options for insurance coverage, such as provisions creating Health Marts or liberalizing Medical Savings Accounts.
4. Enrollees are reimbursed if they win.
5. The Urban Institute conducted case studies for the *Assessing the New Federalism* (ANF) project in Alabama, California, Colorado, Florida, Massachusetts, Michigan, Minnesota, Mississippi, New Jersey, New York, Texas, Washington, and Wisconsin (Kondratas et al. 1998). These states were selected to present a balanced view of state activity and its impact on low-income families. Selection criteria included socioeconomic and political characteristics, availability and generosity of publicly supported health and welfare programs, and geographic diversity. Site visits to the 13 states from July 1996 to May 1997 included numerous interviews with public officials, advocates, associations, and providers.
6. We arrived at this estimate by adding 1997 Medicare enrollment, 1996 federal civilian employment (including part-time but excluding Central Intelligence Agency, Defense Intelligence Agency, seasonal, on call, and National Security Agency staff), 1996 onshore active-duty military personnel, and 1997 veterans, all divided by 1997 population. We then lowered the estimate boundaries by 5 percent to acknowledge possible double-counting in the Medicare and veteran populations.
7. As a rough guide, we looked at the percentage of workers in firms with more than 100 employees across states, since many or most large firms self-insure their health benefits. The rate varies from 39 to 50 percent in the 13 focus states (Liska et al. 1998).
8. Note that the PPO and HMO data in table 4 are from different years and sources. PPO enrollment is underestimated because the in-state enrollment of national PPOs operating in each state is not known.
9. A count of the number of provisions in force in a state is an unsophisticated proxy for the level of regulation, since laws vary in stringency and application, as discussed above. However, it is useful for illustrative purposes.
10. Note that the entities regulated correspond to the earlier discussion of different populations affected—those covered by self-insured plans versus fully insured plans.
11. For details, see AAHP 1998; Nichols and Blumberg 1998; DOL 1997, 1998a, b, and c; Polzer 1999.
12. The bill says this is the "aggregate" amount but does not specify if this represents an annual total, a total for any one enforcement action, or some other total. (H.R. 448 has the same provision and says annual total.) There is also a provision for fines of up to $10,000 for violations of title IV, related to health care research.
13. The U.S. Supreme Court blocked a state claim for punitive damages for negligent administration of a disability policy in *Pilot Life Insurance Co. v. Dedeaux,* 481 U.S. 41 (1987). A good summary of restrictive court interpretations appears in *Scholtens v. Schneider,* 173 Ill. 2d 375 (1996); see also Jacobson and Pomfret 1998.
14. *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645 (1995), and *DeBuono v. NYSA-ILA,* 117 S.Ct. 1747 (1997).
15. The leading case is *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350 (3d Cir. Ct. of Appeals 1995). For a listing of relevant cases, including hyperlinks to opinions, see HARP (1999a).

16. The House Republican bill (H.R. 448) does create new national standards of tort reform for all lawsuits touching upon health care, including those against insurers (title IV). The bill focuses on limiting allowable damages through a "cap" on pain and suffering, along with other provisions. It does not create or destroy any substantive bases for holding managed care plans liable for patient injury.

17. Sec. 302(a) would bar punitive damages where a plan or issuer's decision followed the recommendation of an external reviewer.

18. The Norwood (Republican) bill is identical in its main provisions (H.R. 216, sect. 302) but adds additional explanation of what constitutes discretionary authority as further protection for employers. Defined out of potential employer liability are decisions on what benefits to include in a plan, decisions upholding the recommendation of a treating health care professional, and decisions to extend benefits beyond the specified limits of the plan.

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